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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/704,054	11/01/2000	Robert D'Amato	43170-249244	3798
20583	7590	05/04/2005	EXAMINER	
JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017			COOK, REBECCA	
			ART UNIT	PAPER NUMBER
			1614	

DATE MAILED: 05/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/704,054

Applicant(s)

D'AMATO, ROBERT

Examiner

Rebecca Cook

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 January 2005.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23,25-31 and 33-58 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 23,25-31 and 33-58 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/27/05</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 23, 25-31 and 33-58 are again rejected under 35 U.S.C. 103(a) as being unpatentable over Sugiura et al for the reasons given in the Paper of June 19, 2002.

Applicant argues that Sugiura does not teach what cancer thalidomide might be used for and that at most, it is an invitation to experiment with thalidomide in certain unknown cancer cases. This is not persuasive. Sugiura disclosed that thalidomide had a moderate inhibitory effect on Lewis bladder carcinoma (page 59) and slight inhibiting effect on 6 other tumors. This would render it obvious to use for at least these tumors, especially in patients for whom other treatments had not been successful.

Claims 23, 25-31 and 33-58 are again rejected under 35 U.S.C. 103(a) as being unpatentable over Muckter for the reasons given in the Paper of July 27, 2004.

Applicant argues that the animal studies reported therein do not suggest the claimed use of thalidomide in animals. This is not persuasive. Ace Animals, Inc. (cited for evidentiary purposes only) discloses that the Sprague Dawley rat is a general model for the study of health and disease. Furthermore, a survey of the literature prior to 1993 discloses that Sprague Dawley rats were considered relevant animal models for the study of breast cancer. (See MEDLINE AN 03246378, Kantorowitz et al; MEDLINE AN

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91105904, Thompson et al; MEDLINE AN 88225378, Hershman et al; BIOSIS AN 1990:450534, Rogers et al; BIOSIS AN 1990:220159, Iino et al, cited for evidentiary purposes only).

Claims 23, 25-31 and 33-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mau'ad. Mau'ad (pages 16-32, English language translation) discloses that thalidomide is an effective treatment against many different kinds of cancer.

Applicant argues that in light of the disclosures of all art as a whole, there is no motivation to use thalidomide to treat cancer. This is not persuasive. There are sufficient teachings in the art, as cited above, to render it obvious to one of ordinary skill in the art to use thalidomide to treat cancer.

In view of applicant's argument regarding Grabstald that further random trials of this drug against cancer in man are not indicated and the finding that "No significant degree of antineoplastic activity was demonstrated, although the possibility that a particular type of cancer may show some degree of response" (page 301, right column), one skilled in the art would conclude that while it discloses a reason to try thalidomide to determine its efficacy to treat cancer, Grabstald does not render the use of thalidomide obvious.

In view of applicant's argument regarding what was known by those of ordinary skill in the art at the time of the instant invention regarding the use of immunosuppressive agents to treat cancer, 5,399,363 (Liversidge et al) is withdrawn.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 23, 25-31 and 33-58 are again rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5,629,327. Although the conflicting claims are not identical, they are not patentably distinct from each other because '327 discloses a method of using thalidomide to treat undesired angiogenesis for the reasons given in the Paper of July 27, 2004.

Applicant argues that claim 1 of '327 does not suggest methods of inhibiting tumor formation and metastasis using thalidomide as recited by the pending claims. This is not persuasive. '327 discloses (column 3, lines 8-27) that angiogenesis is prominent in solid tumor formation and metastasis and discloses (column 5, lines 16-27) that it intends to provide treatment for solid tumors and blood-born tumors such as leukemia using thalidomide.

Information Disclosure Statement

Bach, *The Lancet*, could not be considered, since it was not received.

Action Is Final

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on January 27, 2005 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609(B)(2)(i). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Cook whose telephone number is (571) 272-0571. The examiner can normally be reached on Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on (571) 272-0951.

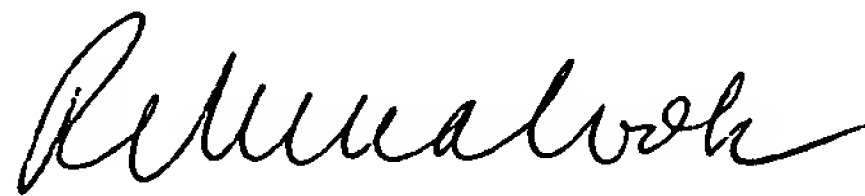
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Renee Jones (571) 272-0547 in Customer Service.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

The official fax number is 571-273-8300.

Rebecca Cook

A handwritten signature in cursive script, appearing to read 'Rebecca Cook', written in black ink.

Primary Examiner
Art Unit 1614

May 2, 2005